present study was to measure the functional status and quality of life in RD patients receiving the biologic agent golimumab in Greece **METHODS:** A descriptive study was conducted estimating the annual Quality-of-Life (QoL) improvement for 148 patients diagnosed with rheumatoid arthritis (RA), psoriatic arthritis (PS) and ankylosing spondylitis (AS). QoL was estimated with standardized questionnaires such as EQ-5D and HAQ questionnaire. In addition, twenty specific parameters including "general health", "severity of pain", "productivity level" etcetera wereassessed on 10-point Likert scale. Data was collected by doctors across the country at 3 month intervals (4 waves of questionnaires during the year). **RESULTS:** Patients with RA reported improved QoL by 14%, followed by 0.67 decrease of average HAQ score. They also reported a 7.5 hours gain of working hours and an overall 14% gain in productivity per week. Patients with AS were estimated to present 30% improvement in general health condition according to their doctors with similar self-reported estimations. Additionally, their QoL was improved by 17%. Similarly, patients with PS estimated their QoL improved by 17% with a 6hr/week gain in working hours otherwise missed, while the average HAQ score fell by 0.71 Findings are in accordance with similar published studies all contributing to the general assumption that patients receiving biological agents experience greater QoL improvement compared to conservative treatment options. **CONCLUSIONS:** Statistical analysis revealed significant improvement of functional status, quality of life, productivity gains and decrease of disease activity for those receiving Golimumab in Greece for all three disease groups. Amongst limitations, both number of the study group and follow-up period should be taken into consideration.

PMS80

QUALITY OF LIFE IN PATIENTS WITH CHRONIC LUMBOSCIATIC SYNDROME IN THE SLOVAK REPUBLIC

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OBJECTIVES: The current prevalence of Chronic Lumbosciatic Syndrome (CLSS) in Slovakia ranges in about 170000 cases. The CLSS has a great impact on quality of life (QoL) and the ability to work too. Till now in Slovakia was not realised the study like this. **METHODS:** 86 patients with CLSS were studied. The "hospital" and the "out-patients clinic" group had 43 vs 43 patients. The average age was 50.36 vs 51.79 y., weight – 61.04 vs 77.95 kg, duration of illness – 5.3 vs 5.0 years, symptoms of illness before diagnosis – 2.27 vs 2.16 years. QoL and the ability to work was evaluated on the numeric scale from 0 to 10 (0 for the worst, 10 for the best) by patients themselves. **RESULTS:** The "hospital" and the "out-patients clinic" group had these results: the average of hospitalisation – 1.51 vs 1.44 times, incapacity to work – 3.06 vs 2.90 months. QoL in the time of good health was 8.2 vs 8.04, in the time of diagnosis – 5.86 vs 6.74, and in the current time – 4.58 vs 3.95. The work ability (WA) had these results: WA in time of good health was 8.97 vs 9.04 in the time of diagnosis – 8.16 vs 8.13, and in the current time – 3.83 vs 3.83. The impact of the treatment on the QoL was 5.37 vs 6.06 and on the patients families QoL it was 6.16 vs 6.13. The willingness to pay for the perfect cure was 477.90 € vs 524.41 € per month (the average salary in Slovakia in 2013 was 824 €). **CONCLUSIONS:** CLSS has a great impact on QoL and on the WA too. There was not statistical difference between both "hospital and out-patient clinic" patients in the QoL and WA. Early diagnosis is important to effective treatment.

PMS81

REASONS FOR TREATMENT DISCONTINUATION OF BIOLOGICS – DEVELOPMENT AND VALIDATION OF A QUESTIONNAIRE

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OBJECTIVES: For patients with rheumatoid arthritis (RA) and inadequate response to traditional therapy, treatment with biologics is recommended to reduce disease progression and improve HRQol. Nevertheless, up to 30% of patients stop treatment on their own initiative. Aim of the study is to develop and validate an instrument to assess reasons for treatment discontinuation of biologics in patients with RA. **METHODS:** We conducted expert interviews with rheumatologists (n=5) to develop a questioning route, which was used in 2 focus groups with a total of 15 RA patients who dropped out therapy (phase 1). Based on these results a draft questionnaire was developed and pre-tested (phase 2; n=6), resulting in the pilot questionnaire. In the validation phase (phase 3) the questionnaire is completed by approx. 200 patients, with an interim analysis planned after recruitment of half the sample size. Quantitative data analyses will focus on psychometric properties: missing data, floor/ceiling effects, factorial validity, distribution of properties. Patients are recruited at 40 German office based rheumatologists, with 5 patients per center. **RESULTS:** The final questionnaire consists of 82 items covering sociodemographic aspects, HRQoL, history of treatment and disease, treatment information, expectations and satisfaction and "reasons for discontinuation". Piloting showed that HRQoL, treatment and working-life aspects have impact on treatment discontinuation. Particularly, information about treatment options, patient-doctor relationship and financial burden were addressed. The questionnaire has proven to be feasible in field-test. Validation phase is currently ongoing; results from the interim analysis will be presented. **CONCLUSIONS:** Interviews with experts and patients demonstrated that treatment discontinuation is triggered by multiple reasons. A targeted developed questionnaire is necessary to identify latent reasons for treatment discontinuation. Furthermore, an "easy-to-use" questionnaire could be used in daily routine to identify patients likely to withdraw treatment and need special patient adherence programs.This research was funded by Pfizer GmbH.

PMS82

ASSESSING WILLIGNESS TO PAY AMONG PSORIASIS AND PSORIATIC ARTHRITIS PATIENTS

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OBJECTIVES: It is estimated that 30% of psoriasis (PSO) patients also develops psoriatic arthritis (PSA). This potential disease evolution brings along new symptoms such as swollen and painful joints and mobility problems. Since both diseases are potentially degenerative, the aim of this study was to measure which group of patients (PSO or PSA) is willing to pay most out of pocket to avoid their health related quality of life (HRQoL) to worsen. **METHODS:** 395 US patients diagnosed with either psoriasis (n=151) or psoriatic arthritis (n=247) completed a questionnaire as part of a broader survey of treatment of PSO/PSA. The questionnaire included the EQ-5D-5L instrument and accompanying VAS. Patients were additionally asked to indicate by reference to the EQ-5D VAS scale the amount of money per month they would be willing to pay for treatments that would prevent a decline in HRQoL by 10 points. Price sensitivity curves were created by means of linear regression analysis that predict the proportion of patients willing to pay a certain amount of $ out of pocket per month. **RESULTS:** For both PSO ($R^2 = 0,82$) and PSA ($R^2 = 0,86$) monthly cost out of pocket (x-variable) was a good predictor of the proportion of patients that is willing to pay a certain amount out of pocket per month (y-variable). Regression models look as follows. For PSO: $y = 0,77e^{-0,005x}$ for PSA: $y = 0,86e^{-0,007x}$. To give a specific example 42% of the PSA patients is willing to pay $100 per month out of pocket whereas this is 47% among PSO patients. **CONCLUSIONS:** PSO patients are prepared to pay more out of pocket on a monthly basis to avoid their HRQoL to worsen than PSA patients. Further research is required to understand what drives this difference.

PMS83

SUSTAINED IMPROVEMENTS IN WORKPLACE AND HOUSEHOLD PRODUCTIVITY AND SOCIAL PARTICIPATION WITH CERTOLIZUMAB PEGOL OVER 96 WEEKS IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS, INCLUDING ANKYLOSING SPONDYLITIS AND NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

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OBJECTIVES: To report the long-term effect of certolizumab pegol (CZP) on workplace and household productivity up to 96 weeks (wks) in patients with axial spondyloarthritis (axSpA), including ankylosing spondylitis (AS, meeting modified New York criteria) and non-radiographic axSpA (nr-axSpA). **METHODS:** The ongoing RAPID-axSpA trial (NCT01087762), is double-blind and PBO-controlled to Wk24, dose-blind to Wk48 and open-label to Wk204. Patients had active axSpA, according to ASAS criteria, including AS and nr-axSpA patients. Patients originally randomized to CZP (200mg Q2W or 400mg Q4W, following 400mg loading dose [LD] at Wks 0, 2, 4) continued on their assigned dose in the OLE; PBO patients entering dose-blind phase were re-randomized to CZP LD followed by CZP 200mg Q2W or CZP 400mg Q4W after Wk24 or, for non-responders, after Wk16. The validated arthritis-specific Work Productivity Survey (WPS; administered Q4W) assessed the impact of axSpA on workplace and household productivity. WPS responses (LOCF imputation) in patients originally randomized to CZP are summarized descriptively over 96 wks. **RESULTS:** 325 patients were randomized, of whom 218 received CZP (200mg Q2W or 400mg Q4W) from Wk0. Of patients randomized to CZP at baseline (BL), 93% completed Wk24, 88% Wk48 and 80% Wk96. At BL, 72% of CZP patients were employed outside of the home. Employed CZP patients reported reductions in workplace absenteeism and presenteeism to Wk24, with continued improvements to Wk96 (BL: mean 1.8 days missed/month, mean 5.2 days with reduced productivity/month vs Wk96: mean 0.6 days missed/month, mean 1.4 days with reduced productivity/month). CZP patients also reported continued improvements in household productivity and social participation to Wk96 in both dose regimens, and similar improvements were observed in AS and nr-axSpA. **CONCLUSIONS:** The initial improvements with CZP in workplace and household productivity and increased participation in social/leisure activities were continued to Wk96 in axSpA, AS and nr-axSpA patients.

PMS84

SUSTAINED IMPROVEMENTS IN WORKPLACE AND HOUSEHOLD PRODUCTIVITY AND SOCIAL PARTICIPATION WITH CERTOLIZUMAB PEGOL OVER 96 WEEKS IN PATIENTS WITH PSORIATIC ARTHRITIS

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OBJECTIVES: To examine the long-term effect of certolizumab pegol (CZP) on workplace and household productivity up to 96 weeks (wks) in patients with active psoriatic arthritis (PsA). **METHODS:** The ongoing RAPID-PsA trial (NCT01087788) is double-blind and PBO-controlled to Wk24, dose-blind to Wk48 and open-label to Wk216. Patients had active PsA and had failed ≥1 DMARD. Patients originally randomized to CZP (200mg Q2W or 400mg Q4W, following 400mg loading dose [LD] at Wks 0, 2, 4) continued on their assigned dose in the OLE; PBO patients entering dose-blind phase were re-randomized to CZP LD followed by CZP 200mg Q2W or 400mg Q4W after Wk24 or, for non-responders, Wk16. The validated arthritis-specific Work Productivity Survey (WPS) administered Q4W from baseline (BL), assessed the impact of PsA on workplace and household productivity in the randomized set. WPS responses (LOCF imputation) in patients originally randomized to CZP groups are summarized descriptively over 96 wks. **RESULTS:** 409 patients were randomized, of whom 273 received CZP 200mg Q2W or CZP 400mg Q4W. Of patients randomized to CZP, 91% completed Wk24, 87% Wk48 and 80% Wk96. In employed patients in both CZP groups (60.8% of all CZP patients at BL), decreases in absenteeism and presenteeism to Wk24 were continued up to Wk96 (BL: mean 2.0 and 1.6 days missed/month in the CZP 200mg Q2W and 400mg Q4W groups, respectively; mean 5.2 and 5.1 days with reduced productivity/month vs Wk96: mean 0.3 and 0.4 days missed/month; mean 0.7 and 1.5 days with reduced productivity/month). Improvements in household productivity and social participation reported in both CZP groups over 24 wks were also maintained to Wk96. **CONCLUSIONS:** The initial improvements

with CZP in workplace and household productivity, and social participation were sustained up to 96 wks in PsA patients.

MUSCULAR-SKELETAL DISORDERS – Health Care Use & Policy Studies

PMS85
MARKET ACCESS OF IMPLANTABLE MEDICAL DEVICES - PART II: DECISION DRIVERS ACROSS GLOBAL MARKETS

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OBJECTIVES: With rising pressures on health care budgets, health technology assessment (HTA) agencies are increasingly scrutinizing medical devices (MDs) for economic benefits in addition to clinical benefits. This level of scrutiny has resulted in many unfavorable recommendations from agencies and only a small proportion of unconditionally favorable reviews. As an extension of our work reported at 2013 ISPOR Annual Congress (Dublin, IR) this study aims to: 1) Identify key criteria cited by HTA agencies as major decision drivers, 2) Note common criteria among reviews that were positive, negative, or positive with reservations, and 3) Analyze temporal or geographic trends among decision drivers. **METHODS:** A review of 68 HTAs and reimbursement decisions of implantable MD with a variety of indications was conducted, focusing on decisions published from 2008-2013 identified by Quintiles' HTA Watch from North America, Europe, and Australia. Clinical, economic, and other factors noted as pivotal to HTA and reimbursement decisions were registered and compared. Importantly, care was exercised to note only the criteria that triggered a HTA to make a favorable or unfavorable decision, as opposed to criteria that were only correlative. **RESULTS:** Key product attributes affecting HTA decisions include 1) sufficiency and quality of evidence, 2) cost offsets and budget impact, 3) adverse event profiles, and 4) comparison to existing alternatives where available. Notab ly, 33% of HTA decisions were negative, with many decisions citing insufficient evidence. Additionally, a majority of favorable HTA decisions were reserved in their recommendations, citing a need for additional evidence to uphold the initially favorable recommendation. The relative importance of economic considerations varied across countries. **CONCLUSIONS:** HTA agencies' scrutiny of sufficiency of evidence, among others, may significantly impact market access of medical devices. As such, manufacturers need careful planning to align evidence development, pricing and access plans with HTA agency, payer and pricing authority requirements.

PMS86
ANTI-TNF BIOSIMILARS INDICATED FOR RHEUMATOID ARTHRITIS ARE INCREASINGLY AVAILABLE IN EUROPE: HOW DO PAYERS AND KEY STAKEHOLDERS PERCEIVE THEM?

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OBJECTIVES: The process of bringing a biosimilar to market in Europe is quicker, easier and cheaper than developing a new biologic. As a class, rheumatoid arthritis (RA) has the greatest number of anti-TNF biosimilar molecules in development, with more expected to follow. This research was focussed on the key issues reported by payers and Key Opinion Leaders (KOLs) in France, Germany and Italy. **METHODS:** Supported by secondary research our study entailed conducting one hour telephone interviews with influential senior payers involved in budgetary decision making at the national and regional level in addition to KOLs. These structured interviews explored how stakeholders perceived the introduction of anti-TNFs biosimilars. **RESULTS:** Payers see anti-TNF biosimilars as an opportunity to reduce the biologic budget but KOLs want to treat more patients within the same budget. Payers in Germany and France reported a greater perception of the efficacy of biosimilars than their counterparts in Italy. Treatment naïve patients are considered most suitable for anti-TNF biosimilars while automatic substitution was not favoured by any respondents. Nonetheless, price played a role and some KOLs stated they may attempt to switch existing patients who have a low risk of acute complications with very close monitoring. **CONCLUSIONS:** Biosimilars may be perceived unequally across markets. Manufacturers are likely to require the use of differentiated value stories when presenting their biosimilar products to payers and KOLs, with the latter more inclined to perceive them as an opportunity to treat more patients with the same expenditure instead of reducing budgets. Manufacturers will likely struggle to encourage the switching of existing patients onto biosimilars without offering a significant discount. In France and Germany, anti-TNF RA biosimilars are currently generating demand that closely matches their increasing prevalence.

PMS87
COMPARISON OF CLINICAL CHARACTERISTICS OF PATIENTS WITH RHEUMATOID ARTHRITIS (RA) RECEIVING BIOLOGIC MONOTHERAPY AND BIOLOGIC-CONTAINING COMBINATION THERAPY IN EUROPE

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OBJECTIVES: To assess the clinical characteristics of patients with RA who received biologic monotherapy ("Mono") or biologic-containing combination therapy ("Combo") in Europe. **METHODS:** A multi-country, multi-center medical chart review study of patients with RA was conducted in Q42012 among physicians in hospitals and private practices to collect de-identified data on patients who were recently treated with a biologic as part of usual care in France/Germany/Italy/Spain/UK. Physicians were screened for duration of practice (3-30yrs) and patient volume (≥2 RA biologic patients/week) and recruited from a large panel to be geographically representative in each country. Eligible patient charts (≥5) were randomly selected from among the patients visiting each center/practice during the screening period. Physicians abstracted date of diagnosis, treatment patterns/dynamics, and symptomatology/disease status. Mono and Combo patients were compared used descriptive statistics. **RESULTS:** 1534 eligible RA patients were assessed; Mono: 428 (28%), Combo: 1106 (72%). Patient characteristics (Mono/Combo) included: age 51.8/51.7; female 71%/75%; weight 68.6/68.5kg; top three comorbidities: dyslipidemia (16%/19%), depression/anxiety (9%/13%), obesity (8%/12%). Time since diagnosis: 68.6/78.2mo. Current line of biologic therapy: first-line 86%/75%, second-line 11%/18%, ≥third-line 3%/6%. Top four biologics used across the two patient groups: etanercept (33%)/adalimumab (30%)/tocilizumab (9%)/certolizumab pegol (7%). Current lab values/disease severity measures: ESR (mm/h) 21.7/23.2; CRP (mg/l) 10.3/10.3; rheumatoid factor (positive) 84%/87%; anti-CCP (positive) 70%/80%; current disease stage per physician judgment: mild 65%/52%, moderate 32%/40%, severe 3%/8%; mean VAS 3.4/3.6; mean HAQ 1.4/1.1; mean DAS 28 3.6/3.3; mean tender joint count 3.5/4.1; mean swollen joint count 2.4/2.6. **CONCLUSIONS:** In this cohort of RA patients in Europe, the majority of patients on monotherapy and combination therapy had mild disease per physician judgment and were on first-line biologic therapy. Lab measures and joint counts indicated only slightly higher disease burden among combination therapy patients. The impact of specific biologic treatments on observed patterns and the need for therapeutic sequencing may warrant further research.

PMS88
COPING WITH A NEW BIOLOGIC PARADIGM: PAYER STRATEGIES FOR THE PURCHASING OF COMPLEX BIOSIMILARS

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OBJECTIVES: In Europe, biosimilars of complex molecules such as monoclonal antibodies have started to enter the market. In this research we aim to provide an understanding of the current expectations for the purchasing of these products as well as an overview of the tools that payers expect to employ to encourage biosimilar use. **METHODS:** Qualitative survey of payers across national, regional and local levels in France, Germany, Italy, Spain, the UK and Netherlands. Collection and analysis of data on (1) current and future attitudes relative to expected biosimilar purchasing systems; and (2) the tools that payers expect to use to drive biosimilar use, assuming this is a payer goal. **RESULTS:** (1) The method of biosimilar purchase in the short term will vary by country, with the majority of countries using tenders to procure these products; (2) While tenders restricting choice of product to a single winner will not be used extensively in the short term, these will be common across most countries in the future; (3) Payers will also use a number of other tools such as formal and informal recommendations, prescription incentives and auditing or prescription targets in order to encourage use of the product they have chosen; (4) New procurement pathways and tools are being developed to introduce biosimilars, as highlighted by the new biosimilar law in Italy which defines a level of discount at the national level. **CONCLUSIONS:** Payer strategies should maximize savings by introducing less expensive biosimilars, but also must consider physician preferences, especially when influenced by potentially valid concerns about lack of data. In order to do this, payers are creating novel purchasing frameworks and tools, and while they are currently reticent to use restrictive methods to encourage use of biosimilars, this is expected to rapidly change in a short timeframe.

PMS89
AN ASSESSMENT OF THE ASSOCIATION BETWEEN RURAL STATUS AND HEALTH SERVICE RESOURCE USE AMONG PATIENTS WITH ANKLE SPRAINS IN ONTARIO

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OBJECTIVES: Despite Ontario's universal health care system, differences exist in health care accessibility and quality across the province. The objective of this study is to assess health care resource utilization for patients with ankle sprains based on rurality. **METHODS:** Data on individuals who sought medical attention for ankle sprains between 2003 and 2011 in Ontario were obtained from multiple databases linked through the Institute for Clinical Evaluative Sciences (ICES). The Rurality Index of Ontario (RIO) was used to measure the rurality level of patients based on their population density and geographic distance to health care facilities. Demographic characteristics were obtained for each of five RIO categories. Health care utilization (number of visits to primary care physicians, specialists and ambulatory care) and physician billing costs were obtained and compared among the RIO categories. **RESULTS:** Between 2003 and 2011, the Ontario Health Insurance Program was billed $64 million and $36 million (2013 CAD) by specialists and general practitioners, respectively, for the treatment of ankle sprains and dislocations. Approximately $116 million was spent on direct and indirect costs of emergency room visits for ankle sprains and dislocations. The largest proportion of rural injuries occurred in the top income quintile. Patients in the most rural RIO category saw specialists least often and had the highest number of ambulatory care visits. However, specialist visits constituted higher costs when compared to GP visits. The highest specialist costs found were for males, elderly patients, and those who sought medical attention during winter. The observed statistical differences in cost of GP visits across RIO categories were not clinically meaningful. **CONCLUSIONS:** The differences in health care utilization between RIO categories may indicate a lack of access to specialist care with those residing in rural areas relying on emergency departments for care. These results may be useful in allocating future resources to better serve rural patients.

PMS90
PREDICTING THE BURDEN OF KNEE ARTHROPLASTY REVISION OVER A 20-YEAR HORIZON

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